K131471

neosteo
EFFICIENT MOBILITY

510(k) Summary

Version 1

Preparation Date:
May 2013

I. SUBMITTER'S INFORMATION

A. 510(k) Owner

NEOSTEO

2 Rue Robert Schuman

44 400 REZE, France

Tel: +33 (0)2 36 56 96 70

Fax: +33 (0)2 51 70 61 34

AUG 2 8 2013

B. Contact Person

JD Webb

The Orthomedix Group, Inc.

1001 Oakwood Blvd

Round Rock, TX 78681

Tel: 512 388 0199

Fax: 512 692 3699

Email: jdwebb@orthomedix.net

C. Date of Preparation of the 510(k) Summary

20th May 2013

neosteo EFFICIENT MOBILITY

510(k) Summary

Version 1

Preparation Date:
May 2013

II. DEVICE IDENTIFICATION

A. Trade or proprietary name

Self-Compressive Screw

B. Common or usual name

Self-compressive screw range

C. Classification name

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040, Product code HWC)

D. Class

II

E. Product code

HWC

F. CFR section

21 CFR 888.3040

G. Device panel

Orthopedic

H. Predicate devices

The Self-Compressive Screw is similar to the following predicate device which has been cleared via the premarket notification process: Newclip Foot and Hand Motion System (K091118).

III. DEVICE DESCRIPTION

The Self-Compressive Screw consists of screws available in several diameters and lengths.

All the implants are made of titanium alloy.

The fixation is provided thanks to the threading of the screw, which allows compression.

A. Materials

Titanium alloy per ASTM F136

IV. INTENDED USE

The Self-Compressive Screws are intended for the fixation of bone fractures and for bone reconstruction in forefoot surgery.

V. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

The Self-Compressive Screw is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.

VI. NON-CLINICAL TEST SUMMARY

The following mechanical tests were performed:

- Resistance to torsion according to ASTM F543 – Annex 1
- Pull-out strength according to ASTM F543 – Annex 3.

The results of these testing indicate that the current Self-Compressive Screw is equivalent to predicate device.

VII. CLINICAL TEST SUMMARY

No clinical studies were performed.

VIII. CONCLUSIONS NON-CLINICAL AND CLINICAL

NEOSTEO considers the current Self-Compressive Screw to be equivalent to the predicate device listed above. This conclusion is based on the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Neosteo Efficient Mobility
% The Orthomedix Group, Incorporated
Mr. JD Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K131471
Trade/Device Name: Self-Compressive Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 27, 2013
Received: May 30, 2013

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131471

neosteo
EFFICIENT MOBILITY

Indication For Use Statement

Version 1

Preparation Date:
April 2013

510(k) Number (if known): K131471

Device Name: Self-Compressive Screws

Indications for Use:

The Self-Compressive Screws are intended for the fixation of bone fractures and for bone reconstruction in forefoot surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices